

REMARKS

Claims 1-13, 15-29, 32-35, and 41-62 are currently pending. The Examiner has asserted several rejections.

- I. Claims 1-13, 15-29, 32-35, and 41-62 are rejected under 35 USC § 112, ¶1 as allegedly failing to comply with the enablement requirement.
- II. Claims 1-28, 41-56 are rejected under 35 USC 103(a) as allegedly being unpatentable over Mikkelsen et al. Nature 20(9):2249-2255 (1992); Laursen et al., Gene 198(1-2):367-372 (1997); in view of Golovan et al., Nat. Biotechnol. 19(5):429-433, (2001); Golovan et al., Nat. Biotechnol. 19(8):741-745 (2001); Swenson et al., In: Dukes' Physiol. Domestic Animals, 11th Ed., Comstock Publ., Ithaca NY, pp 399-400, (1993); Lubon et al., Transf Med Rev. X(2):131-141 (1996); Lubon et al., US Pat No. 5,880,327; and Coppes et al., Rad Res. 153:339-346 (2000).
- III. Claims 29, 32-35 are rejected under 35 USC 103(a) as allegedly being unpatentable over Mikkelsen et al. Nature 20(9):2249-2255 (1992); Laursen et al., Gene 198(1-2):367-372 (1997); in view of Golovan et al., Nat. Biotechnol. 19(5):429-433, (2001); Golovan et al., Nat. Biotechnol. 19(8):741-745 (2001); Swenson et al., In: Dukes' Physiol. Domestic Animals, 11th Ed., Comstock Publ., Ithaca NY, pp 399-400, (1993); Lubon et al., Transf Med Rev. X(2):131-141 (1996); Lubon et al., US Pat No. 5,880,327; and Coppes et al., Rad Res. 153:339-346 (2000) and in further in view of Deboer et al., US Pat No. 6,140,552..

I. The Claims Are Enabled

The Examiner states that, in regards to Claims 1-13, 15-29- 32-35, and 41-62, the specification:

... does not reasonably provide enablement for a transgenic non-human mammal by way of the claimed methods.

Office Action pg 2. The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claims 1, 20, & 29 to recite

“a transgenic caprine”. *Applicants’ Specification, Original Claim 5*. Further, Claims 1, 20 & 29 are amended to recite “a bovine salivary gland protein promoter”. *See, Applicants’ Specification, pg 33*, in view of previously submitted Erickson Declaration and The Second Wheeler Declaration (*infra*).

The Applicants find that the Examiner has admitted that such an embodiment is enabled:

... the specification, which being enabling for a transgenic goat comprising a bSP30a or a bSP30b promoter, wherein said promoter is operably linked to an exogenous nucleic acid encoding at least one transgenic polypeptide ...

Office Action, pg. 2, and fulfills the statutory requirements for a genus claim:

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation.

MPEP § 2164.02: Working Example. The Applicants submit that the The Erickson Declaration provides the necessary ‘representative examples’ to support a bovine salivary gland protein genus. The Examiner is respectfully reminded that The Erickon Declaration provided data showing that a recombinant protein was secreted into caprine saliva using either a bSP30A or a bSP30B promoter. The Applicants believe that these examples are consistent with well settled case law establishing that the number of required species to enable a genus claim is determined by circumstances. *In re Shokal*, 113 USPQ 283 (CCPA 1957); *In re Soll*, 97 F2d 623, 38 USPQ 189; and *In re Wahlforss* 117 F2d 270, 48 USPQ 397. For example, in a small genus (i.e., for example, a genus of bovine salivary gland protein promoters), coupled with a lack of undue experimentation, current patent law suggests that a relatively small number of examples are sufficient to establish the genus.

Further, the Applicants submit that the specification does provide “a statement applicable to the genus as a whole”.

Particularly useful regulatory regions for expression in saliva are promoters that are active in cells of salivary glands ... particularly ... bovine ...

Applicants’ Specification pg 33 ln 7-13. The Applicant’s teaching is supported by one having ordinary skill in the art stating that at the time of filing of the present invention the known genus of bovine salivary gland protein promoters was limited to the bSP30A and bSP30B promoters. *The Second Wheeler Declaration, ¶ 3*.

In light of these amendments, the Applicant has concomitantly canceled Claims 2-5, 22, 24-26, 32 and 35-62. Amendments to maintain proper antecedent basis have been made in Claims 6-19 and 27. These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Examiner is respectfully requested to withdraw the present rejection.

II. The Claims Are Not Obvious

The Examiner asserts that the pending claims are obvious under a combination of references listed above. The Applicants disagree and believe that both obviousness rejections presented in the present office action are moot in light of the above claim amendments, made for other reasons. In particular, the Applicants believe that the presently amended claims fall within the Examiner's disclaimer regarding the scope of the obviousness rejection:

To the extent the instant claims read on a transgenic non-human mammal with claimed characteristics or a method for creating said transgenic non-human mammal *other than a transgenic goat comprising a bSP30a or a bSP30b promoter ... the following rejection over the prior art is applicable.*


Office Action pg 8 [underlining in original, italics added]. As such, the Examiner is respectfully requested to withdraw the present rejection.

CONCLUSION

The Applicant believes that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above and pass the remaining claims to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect at 781-828-9870.

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By: _____



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